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CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 1277

Introduced by Assembly Members Hill and Perea
(Coauthors: Assembly Members Alejo, Fletcher, Pan, and Smyth)
(Coauthors: Senators Blakeslee and Padilla)

February 18, 2011

An act to amend Sections 111550, 111635, and 111640 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1277, as amended, Hill. Sherman Food, Drug, and Cosmetic Law.

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices, and is administered by the State Department of Public Health. The law prohibits the sale, delivery, or giving away of any new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the ~~federal~~ *Federal* Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval

application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.

The Sherman Food, Drug, and Cosmetic Law requires the department to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

This bill would revise the above-described prohibition to also apply to a new biologic product for which a license has been issued under federal law.

Existing law also requires the department to inspect the place of business of each licensed person *prior to issuance of the license and, thereafter,* once every 2 years, unless the United States Food and Drug Administration inspected the place of business within the previous 2 years.

This bill would, instead, require each place of business to submit to the department ~~written~~ documentation ~~pertaining to an inspection of~~ *that evidences that* the place of business *is operating pursuant to a valid establishment registration issued* by the United States Food and Drug Administration, *as prescribed, or is in compliance with audits conducted pursuant to specified standards,* prior to the department issuing the place of business a license. This bill would authorize the business to request specified written verification from the department that its place of business was approved by the department *based upon specified information* and require the department to provide a prescribed written response.

Existing law authorizes any authorized agent of the department to enter and inspect specified locations, as prescribed, for purposes of enforcement of the Sherman Food, Drug, and Cosmetic Law.

This bill would, *instead,* require the department to make these investigations or inspections ~~when~~ *only under specified circumstances, including when the department makes a determination that the health and safety of the public is at risk,* notification has been sent by the United States Food and Drug Administration of a recall action, or when the United States Food and Drug Administration has requested assistance for enforcement activities.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 111550 of the Health and Safety Code is amended to read:

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).

(3) A new device that is reported under Section 510(k) of the federal act ~~(21 U.S.C. Sec. 360)~~ *(21 U.S.C. Sec. 360(k)), or exempted therefrom pursuant to 21 U.S.C. Sec. 360(m),* or for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

~~(c) It is the intent of the Legislature to preclude the department from requiring a person who intends to sell, deliver, or give away any new drug or device that meets the federal requirements described in subdivision (a) to also obtain an approval pursuant to subdivision (b), except to the extent that the department requires documentation that the federal requirements are met.~~

SEC. 2. Section 111635 of the Health and Safety Code is amended to read:

111635. (a) Prior to issuing a license required by Section 111615 *to any place of business*, the department shall receive from each place of business ~~written documentation pertaining to an inspection of the place of business by the United States Food and Drug Administration~~ *documentation that evidences that the place of business is operating pursuant to a valid establishment registration issued by the United States Food and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) and Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 374), or is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000:2005, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, or similar standards identified by the department by regulation*.

~~(b) A business licensed under Section 111615 may request written verification from the department that its place of business was approved by the department where the United States Food and Drug Administration's inspection was utilized as the basis for license approval. The department shall provide the business with a written response that its place of business has been approved for a license under state law based on its passage of a federal inspection.~~

(b) Upon request by a place of business licensed under Section 111615, the department shall provide written verification that the department issued the license based on documentation that evidences that the place of business is operating pursuant to a valid establishment registration issued by the United States Food

and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) and Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 374), or is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000:2005, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, or similar standards identified by the department by regulation.

SEC. 3. Section 111640 of the Health and Safety Code is amended to read:

111640. ~~The~~ *With respect to drugs and devices, the* department shall make investigations or inspections authorized by Article 2 (commencing with Section 110140) of Chapter 2 ~~when notification has been sent by the United States Food and Drug Administration of a recall action or when the~~ *only when any of the following occur:*

(a) The department makes a determination that the health and safety of the public is at risk.

(b) A complaint has been registered with the department and the department makes a determination that the public health and safety is at risk.

(c) A notification has been sent by the United States Food and Drug Administration of any recall action memorandum.

(d) The United States Food and Drug Administration has requested assistance for enforcement activities, including, but not limited to, embargoes, seizures, or injunctions.

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